TÜV SÜD Italia

CERTIFICATO

Nr. 50 100 5099 Rev.011

SI ATTESTA CHE / *THIS IS TO CERTIFY THAT*

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

DIESSE DIAGNOSTICA SENESE S.P.A.

SEDE LEGALE:
REGISTERED OFFICE:

VIALE DECUMANO 36
IT - 20157 MILANO (MI)

SEDI OPERATIVE: **VEDI ALLEGATO 1** / *OPERATIONAL SITES:* ***SEE ANNEX 1***

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

Progettazione e sviluppo, fabbricazione, immissione in commercio, distribuzione di reagenti diagnostici in vitro. Progettazione e sviluppo, gestione della fabbricazione, immissione in commercio, distribuzione, installazione ed assistenza tecnica di strumenti diagnostici in vitro per analisi cliniche (EA 12, EA 19, EA 29)

Design and development, production, sales and distribution of in vitro diagnostic reagents. Design and development, production management, sales, distribution and servicing of in vitro diagnostic equipment for clinical analyzes (EA 12, EA 19, EA 29)

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Validità / *Validity*

Dal / From: **2025-04-17**

Al / To: **2028-04-16**

Data emissione / *Issuing Date*

2025-01-27

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2005-05-30

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

Italia

ALLEGATO 1 AL CERTIFICATO NR **50 100 5099 Rev.011**
*ANNEX 1 TO CERTIFICATE NO **50 100 5099 Rev.011***

IL CERTIFICATO NR 50 100 5099 Rev.011 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
THE CERTIFICATE N *50 100 5099 Rev.011 COVERS ALSO THE FOLLOWING OFFICES:*

DIESSE DIAGNOSTICA SENESE S.P.A.

Diesse Diagnostica Senese SpA Strada dei Laghi 39 53035 Monteriggioni (SI) Italy	Progettazione e sviluppo, fabbricazione, immissione in commercio, distribuzione di reagenti diagnostici in vitro. Progettazione e sviluppo, gestione della fabbricazione, immissione in commercio, distribuzione, installazione ed assistenza tecnica di strumenti diagnostici in vitro per analisi cliniche *Design and development, production, sales and distribution of in vitro diagnostic reagents. Design and development, production management, sales, distribution and servicing of in vitro diagnostic equipment for clinical analyzes*

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

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Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Validità /*Validity*

Dal / From: **2025-04-17**

Al / To: **2028-04-16**

Data emissione /
Issuing Date

2025-01-27

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2005-05-30

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2025-04-16
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2025-04-16*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

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

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 056726 0001 Rev. 02

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

Certification Mark:

Scope of Certificate: **Design and development, production and distribution of in vitro diagnostic reagents for Immunochemistry (Immunology), haematology, infectious disease and design and development, production, distribution, installation and servicing of related in vitro diagnostic instruments.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 056726 0001 Rev. 02

Report No.: ITA200220003745

Valid from: 2025-05-08
Valid until: 2028-05-07

Date, 2025-01-27

Christoph Dicks
Head of Certification/Notified Body

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 056726 0001 Rev. 02

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies): **Diesse Diagnostica Senese SpA**
Strada dei Laghi 39, 53035 Monteriggioni (SI), ITALY

See scope of certificate

/

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 056726 0006 Rev. 03

Manufacturer:

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

SRN Manufacturer - IT-MF-000013311

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 056726 0006 Rev. 03

Report No.:	ITA200220005356_CN1
Preceding Certificate No.:	V12 056726 0006 Rev. 02
Valid from:	2024-10-11
Valid until:	2027-06-26
Date of Initial Issuance:	2023-04-26

Marta Carnielli
Head of Certification IVD

Issue date: 2024-10-11

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BS-IVDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 056726 0006 Rev. 03

Classification:	Class C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0501 - Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

Classification:	Class C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer IVR 0603 - Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances

Classification:	Class C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3001 - In vitro diagnostic devices which require knowledge regarding agglutination tests
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents IVR 0506 - Other devices intended to be used to determine markers of infections/immune status

Classification:	Class B
Device Group:	W0105 - INFECTIOUS DISEASES
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

Classification:	Class B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification: Class B

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EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 056726 0006 Rev. 03

Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0604 - Other devices intended to be used for a specific disease
Classification:	Class B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0605 - Devices intended to be used for monitoring of levels of medicinal products, substances or biological components
Classification:	Class B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY) W0202 - HEMATOLOGY / HISTOLOGY / CYTOLOGY INSTRUMENTS
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers
The validity of this certificate depends on conditions and/or is limited to the following:	\

Revision History:

Rev.	Dated	Report	Description
00	2023-04-26	ITA1980324_CN	Supplemented: Device(s)/group of device(s) added
01	2023-10-16	ITA1980324_CN2	Supplemented: Device(s)/group of device(s) added
02	2024-06-03	ITA200220002142_CN2	Supplemented: Device(s)/group of device(s) added
03	2024-10-11	ITA200220005356_CN1	Supplemented: Device(s)/group of device(s) added

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