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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. 01

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. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 056726 0006 Rev. 01

Report No.:	ITA1980324_CN2
Preceding Certificate No.:	V12 056726 0006 Rev. 00
Valid from:	2023-10-16
Valid until:	2027-06-26
Date of Initial Issuance:	2023-04-26

Marta Carnielli
Head of Certification IVD

Issue date: 2023-10-16

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Classification:	Class C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
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 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

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 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
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

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No. V12 056726 0006 Rev. 01

Classification:	Class B
Device Group:	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

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