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

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 075369 0072 Rev. 04

Manufacturer:

SD Biosensor, Inc.
C-4th&5th, 16, Deogyeong-daero
1556beon-gil, Yeongtong-gu
Suwon-si, Gyeonggi-do 16690
REPUBLIC OF KOREA

SRN Manufacturer - KR-MF-000009168

Authorized Representative:

MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7, 66386 St. Ingbert, GERMANY

The quality management system has been evaluated in accordance with Regulation (EU) 2017/746, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class A devices in sterile conditions are covered by this certificate, the audit was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.
If class B or C excluding self-/near-patient-testing, or class C companion diagnostics devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class D devices, class B or C self-/near-patient testing, or class C companion diagnostics devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

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:V13 075369 0072 Rev. 04

Report No.: 713372953_CN02/ 74973020_CN02
Preceding Certificate No.: V13 075369 0072 Rev. 03

Valid from: 2026-03-25
Valid until: 2030-03-16
Date of Initial Issuance: 2025-09-11

Marta Carnielli
Head of Certification IVD

Issue date: 2026-03-25

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Certificate No. V13 075369 0072 Rev. 04

Classification:	Class B
Device Group:	IVR 0503 - Infectious agent detection: Presence of, or exposure to an infectious agent including sexually transmitted agents
Device Properties:	IVS 1001 - Devices intended to be used for near-patient testing
Intended Purpose:	See product certificate
Classification:	Class B
Device Group:	IVR 0606 - Physiological status and therapeutic measures: Disease staging
Device Properties:	IVS 1001 - Devices intended to be used for near-patient testing IVS 1002 - Devices intended to be used for self-testing
Intended Purpose:	See product certificate
Classification:	Class B
Device Group:	IVR 0503 - Infectious agent detection: Presence of, or exposure to an infectious agent including sexually transmitted agents
Intended Purpose:	Devices intended to be used to detect the presence of, or exposure to an infectious agent
Classification:	Class B
Device Group:	IVR 0605 - Physiological status and therapeutic measures: Medicinal products, substances or biological components
Intended Purpose:	Devices intended to be used for monitoring of levels of medicinal products, substances or biological components
Classification:	Class B
Device Group:	IVR 0606 - Physiological status and therapeutic measures: Disease staging
Intended Purpose:	Devices intended to be used for non-infectious disease staging
Classification:	Class B
Device Group:	IVR 0607 - Physiological status and therapeutic measures: Pregnancy or fertility testing
Intended Purpose:	Devices intended to be used for detection of pregnancy or fertility testing
Classification:	Class C
Device Group:	IVR 0602 - Physiological markers: Specific disease
Device Properties:	IVS 1001 - Devices intended to be used for near-patient testing IVS 1002 - Devices intended to be used for self-testing
Intended Purpose:	See product certificate
Classification:	Class C
Device Group:	IVR 0606 - Physiological status and therapeutic measures: Disease staging
Device Properties:	IVS 1001 - Devices intended to be used for near-patient testing IVS 1002 - Devices intended to be used for self-testing
Intended Purpose:	See product certificate

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EU Quality Management System Certificate

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 075369 0072 Rev. 04

Classification:	Class C
Device Group:	W0102 + IVP 3007 - Immunochemistry
Intended Purpose:	IVD Reagents for Immunochemistry
Classification:	Class C
Device Group:	W0105 + IVP 3007 - Infectious diseases
Intended Purpose:	IVD Reagents for Infectious diseases
Classification:	Class C
Device Group:	W0105 + IVP 3011 - Infectious diseases
Intended Purpose:	IVD Reagents for Infectious diseases
Classification:	Class D
Device Group:	IVR 0503 - Infectious agent detection: Presence of, or exposure to an infectious agent including sexually transmitted agents
Device Properties:	IVS 1001 - Devices intended to be used for near-patient testing
Intended Purpose:	See product certificate
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2025-09-11	713372848_CN	Supplemented: Device(s)/group of device(s) added Administrative merge / transfer to new Certificate Type
01	2025-11-24	713372953CN_01	Supplemented: Device(s)/group of device(s) added
02	2026-03-04	72446667_3_V13	Supplemented: Device(s)/group of device(s) added
03	2026-03-17	74973020_CN01	Supplemented: Device(s)/group of device(s) added
04	2026-03-25	713372953_CN02/ 74973020_CN02	Supplemented: Device(s)/group of device(s) added

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