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

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

## Certificate No. V13 082517 0008 Rev. 01

**Manufacturer:** **FRIZ Biochem GmbH**
Floriansbogen 2-4
82061 Neuried
GERMANY

SRN Manufacturer - DE-MF-000017533

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 082517 0008 Rev. 01

| | |
|---|---|
| **Report No.:** | 713404358 |
| **Preceding Certificate No.:** | V13 082517 0008 Rev. 00 |
| **Valid from:** | 2026-04-20 |
| **Valid until:** | 2030-03-17 |
| **Date of Initial Issuance:** | 2026-01-26 |

Marta Carnielli
Head of Certification IVD

**Issue date:** 2026-04-20


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

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

## Certificate No. V13 082517 0008 Rev. 01

| | |
|---|---|
| **Classification:** | Class C |
| **Device Group:** | W0105 + IVP 3011 - Infectious diseases |
| **Intended Purpose:** | IVD Reagents for Infectious diseases |
| **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 |
| **The validity of this certificate depends on conditions and/or is limited to the following:** | -none- |

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2026-01-26 | 713384607_CN | Supplemented: Device(s)/group of device(s) added<br>Administrative merge / transfer to new Certificate Type |
| 01 | 2026-04-20 | 713404358 | Reduced: Device(s)/group of device(s) removed<br>Supplemented: Device(s)/group of device(s) added |



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®