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

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 071067 0008 Rev. 00

**Manufacturer:** **Liofilchem S.r.l.**
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALY

**SRN Manufacturer:** Not available at the issuance date of this certificate

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 071067 0008 Rev. 00

**Report No.:** ITA1674857

**Valid from:** 2022-07-25

**Valid until:** 2027-07-24

Digitally signed by Ceaicovschi Tudor
Date: 2026.02.23 16:28:02 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2022-07-25


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

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## No. V12 071067 0008 Rev. 00

| | |
|---|---|
| **Classification:** | B |
| **Device Group:** | W0104 - MICROBIOLOGY (CULTURE) |
| **Intended Purpose:** | IVR 0505 - Devices intended to be used to grow/isolate/identify and handle infectious agents |

| | |
|---|---|
| **Classification:** | B |
| **Device Group:** | W0104 - MICROBIOLOGY (CULTURE) |
| **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:** | C |
| **Device Group:** | W0104 - MICROBIOLOGY (CULTURE) |
| **IVP Code:** | IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry |
| **Intended Purpose:** | IVR 0505 - Devices intended to be used to grow/isolate/identify and handle infectious agents |

| | |
|---|---|
| **The validity of this certificate depends on conditions and/or is limited to the following:** | \ |


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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

# C E R T I F I C A T E

## No. QS6 071067 0007 Rev. 04

**Certificate Holder:** **Liofilchem S.r.l.**
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALY

**Certification Mark:**

**Scope of Certificate:** **Design and Development, Production and Distribution of In-Vitro Diagnostic Culture Media for Bacteriology, Mycology and Parasitology, In-Vitro Diagnostic Controls/Standards/Calibrators for Microbiology, In-Vitro Diagnostic Identification and Susceptibility Testing, and Microbiology Tests**

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

**Regulatory Authority(ies):** **Australia TGA, Brazil ANVISA, Health Canada, 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 071067 0007 Rev. 04
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F002916**
**Report No.:** **ITA200220002478**
**Effective Date:** **2025-03-11**
**Expiry Date:** **2028-03-10**


**Date of Issue:** 2025-01-10

( Renee Walker )
Director, US Certification Body, MHS

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# C E R T I F I C A T E

## No. QS6 071067 0007 Rev. 04

**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

**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):**

**Liofilchem S.r.l.**
Via Scozia, 64026 Roseto degli Abruzzi (TE), ITALY

**Liofilchem S.r.l.**
Via Uruguay, 64026 Roseto degli Abruzzi (TE), ITALY


**Date of Issue:** 2025-01-10

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# C E R T I F I C A T E

## No. QS6 071067 0007 Rev. 04

**Facility Scopes:**

**Liofilchem S.r.l.**
Via Scozia, 64026 Roseto degli Abruzzi (TE), ITALY

Production of In-Vitro Diagnostic Culture Media
for Bacteriology, Mycology and Parasitology
REPs Facility ID: F002916

**Liofilchem S.r.l.**
Via Uruguay, 64026 Roseto degli Abruzzi (TE), ITALY

Design and Development, Production and Distribution
of In-Vitro Diagnostic Culture Media for Bacteriology,
Mycology and Parasitology, In-Vitro Diagnostic
Controls/Standards/Calibrators for Microbiology,
In-Vitro Diagnostic Identification and Susceptibility
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