



America

CERTIFICATE

No. QS6 071067 0007 Rev. 02

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

Certification Mark:



Scope of Certificate: Design, Development, Manufacture and Distribution of In-Vitro Diagnostic Medical Devices: Microbial Identification and Susceptibility Testing Systems, Antibiotic Minimum Inhibitory Concentration Test Strips, Antibiotic Discs, Dehydrated and Ready To-Use Culture Plasma Protein Determination Kits

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. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: F002916

Effective Date: 2022-03-14

Expiry Date: 2025-03-10

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Date of Issue: 2022-03-23

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

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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. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

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

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Facility Scopes:

Liofilchem S.r.l.

Via Scozia, 64026 Roseto degli Abruzzi (TE), ITALY

Manufacture and Distribution of In-Vitro Diagnostic Medical Devices: Dehydrated and Ready-To-Use Culture Media
REPs Facility ID: F002916

Liofilchem S.r.l.

Via Uruguay, 64026 Roseto degli Abruzzi (TE), ITALY

Design, Development, Manufacture and Distribution of In-Vitro Diagnostic Medical Devices: Microbial Identification and Antimicrobial Susceptibility Testing Systems, Antibiotic Minimum Inhibitory Concentration Test Strips, Antibiotic Discs, Dehydrated and Ready-To-Use Culture Media, Plasma Protein Determination Kits
REPs Facility ID: F002916

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