MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 071067 0007 Rev. 00

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 Antimicrobial Susceptibility Testing Systems, Antibiotic Minimum Inhibitory Concentration Test Strips, Antibiotic Discs, Dehydrated and Ready-To-Use Culture Media, Plasma Protein Determination Kits**

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

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. 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 https://www.tuev-sued.de/product-testing/certificates

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

DUNS No: **43-534-2134**

Effective Date: **2019-03-11**

Expiry Date: **2022-03-10**

Date of Issue: 2019-03-18

(Arie Henkin)
Manager, Certification Body MHS
TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

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

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820
- 21 CFR Part 821

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):

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

Liofilchem S.r.l.
Contrada Piane Vomano, Traversa di Via Grecia, 64026 Roseto degli Abruzzi (TE), ITALY

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Facility Scopes:

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

Production of In-Vitro Diagnostic Medical Devices: Culture Media for Bacteriology
DUNS No: 43-534-2134

Liofilchem S.r.l.
Contrada Piane Vomano, Traversa di Via Grecia, 64026 Roseto degli Abruzzi (TE), Italy

Design and Development, Production and Sale of In-Vitro Diagnostic Medical Devices: Culture Media for Bacteriology, Identification and Susceptibility Testing Systems, Kits for Plasma Protein Determination; Distribution of Other In-Vitro Diagnostic Medical Devices
DUNS No: 43-534-2134

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