



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Lincotek Trento S.p.A

Loc.Ciré-Via al Dos de la Roda 60

Pergine Valsugana

Trento 38057 Italy

Holds Certificate Number: MD 813822

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and development, production of additive manufacturing, air / vacuum plasma spray coating and surface treatment, cleaning, packaging and control of outsourced machining surface treatment and sterilization of implantable medical devices and instruments in the fields of orthopaedics and dentistry.

Testing of coatings and additive manufactured parts on behalf of Third Parties. Manufacture and distribution of Hydroxyapatite powder.

Transfer from DEKRA, certificate identity number 2071421

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-03-07 Effective Date: 2025-03-07 Latest Revision Date: 2025-03-07 Expiry Date: 2026-11-01

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Certificate No: MD 813822

Location Registered Activities

Lincotek Trento S.p.A Loc.Ciré-Via al Dos de la Roda 60

Pergine Valsugana

Trento 38057 Italy

Design and development, production of additive

manufacturing, air / vacuum plasma

spray coating and surface treatment, cleaning, packaging and

control of outsourced machining

surface treatment and sterilization of implantable medical

devices and instruments in the fields

of orthopaedics and dentistry. Testing of coatings and

additive manufactured parts on behalf of

Third Parties. Manufacture and distribution of Hydroxyapatite

powder.

Lincotek Trento S.p.A Loc.Ciré-Via Ai Manfredi 27

Pergine Valsugana

Trento 38057 Italy

Air plasma and vacuum spray coating of implants

Lincotek Trento S.p.A Loc.Ciré-Via Ai Manfredi 47

Pergine Valsugana

Trento 38057 Italy

Air plasma spray coating of implants. Warehouse location for: storage of spare parts, raw materials and packaging materials.

Lincotek Trento S.p.A Via Dante 300 Pergine Valsugana

Trento 38057 Italy

Additive Manufacturing of metallic device. Laboratory analysis, characterization of coatings and additive manufactured parts. Manufacture of Hydroxyapatite powder. Warehouse location for: raw materials.

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