

CERTIFICATE

Number: 2071421

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Lincotek Trento S.p.A.

Loc. Ciré - Via al Dos de la Roda, 60
38057 Pergine Valsugana (TN)
Italy

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

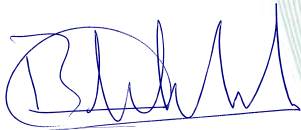
Scope:

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 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.

Certificate expiry date: 1 November 2026
Certificate effective date: 1 November 2023
Certified since: 1 November 2005

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Certification Manager

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ADDENDUM

To certificate: 2071421

The management system of the organization(s) and/or location(s) of:

Lincotek Trento S.p.A.

Loc. Cire - Via al Dos de la Roda, 60
38057 Pergine Valsugana (TN)
Italy

Certified organization(s) and/or locations:

Different scope

Lincotek Trento S.p.A.
(LAT)
Via Dante 300
38057 Pergine Valsugana
Italy

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

Lincotek Trento S.p.A.
(LMT2)
Loc. Ciré - Via Ai Manfredi, 27
38057 Pergine Valsugana
Italy

Air plasma and vacuum spray coating of implants

Lincotek Trento S.p.A.
(LMT3)
Loc. Ciré - Via Ai Manfredi, 47
38057 Pergine Valsugana
Italy

Air plasma spray coating of implants.

Warehouse location for: storage of spare parts, raw materials
and packaging materials.

Addendum expiry date: 1 November 2026

Addendum effective date: 1 November 2023