

# 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:

Research, design and development and purchase of surface coatings, coating and surface treatment of medical devices (dental implants, orthopedic implants, spinal implants and fixation devices for traumatology).

Cleaning and packaging under controlled environmental conditions of coated implants.

Lab analysis, characterization of coatings and additive manufactured parts on behalf of Third Parties.

Sales of service activities on medical devices, including control on outsourced sterilization activities on behalf of Third Parties.

Manufacture and distribution of Hydroxyapatite powder. Additive manufacturing of medical devices.

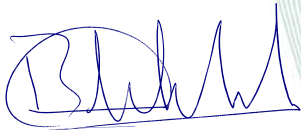
Certificate expiry date: 1 November 2020

Certificate effective date: 28 January 2020

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.A. van Vugt  
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. Ciré - Via Al Dos de la Roda  
38057 Pergine Valsugana (TN)  
Italy

Certified organization(s) and/or locations:

Different scope

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

Additive manufacturing of medical devices.

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

Bone substitution manufacturing, air plasma and vacuum spray coating of orthopedic implants

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

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

Addendum expiry date: 1 November 2020

Addendum effective date: 28 January 2020