CERTIFICATE

Number: 2071421

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

Eurocoating S.p.A.

Via Al Dos de la Roda, 60 Z.I. Cire 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. Design and development, manufacture and distribution of bone substitute devices

Certificate expiry date: 1 November 2020 Certificate effective date: 1 March 2019 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

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 2071421

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

Eurocoating S.p.A.

Via Al Dos de la Roda, 60 Z.I. Cire 38057 Pergine Valsugana (TN) Italy

Certified organization(s) and/or locations:

Different scope

Eurocoating S.p.A. Via Dante 300 38057 Pergine Valsugana (TN) Italy Additive manufacturing of medical devices.

Eurocoating S.p.A. Via Ai Manfredi, 27 38057 Cirè Di Pergine Valsugana (TN) Italy Bone substitution manufacturing, air plasma and vacuum spray coating of orthopedic implants

Eurocoating S.p.A. Via Al Manfredi, 47 38057 Cirè Di Pergine Valsugana (TN) Warehouse location for: storage of spare parts, raw materials and packaging materials.

Addendum expiry date: 1 November 2020 Addendum effective date: 1 March 2019