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 13485:2012

Scope:

Research, design and development and purchasing 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 on behalf of Third Parties.

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

Manufacturing and distribution of Hydroxyapatite powder. Additive manufacturing of medical devices. Design and development, manufacturing and distribution of bone substitute devices.

Certificate expiry date: 1 March 2019
Certificate effective date: 20 November 2017
Certified since: 1 November 2005

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

DEKRA Certification B.V.

drs. G.J. Zoetbrood Managing Director ing. A.A.M. Laan 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 38057 Pergine Valsugana (TN) Italy

Certified additional organization(s) and/or locations:

Different scope

Eurocoating S.p.A. Via Dante 300 Pergine

Additive manufacturing of medical devices

Eurocoating S.p.A. Via Al Manfredi, 27

38057 Cire Di Pergine Valsugana (TN)

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

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

Addendum expiry date: 1 March 2019

Addendum effective date: 20 November 2017