EC CERTIFICATE

Number: 2189673CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

SINT-TECH

Parc Européen d'Entreprises
Rue Richard Wagner
63200 Riom
France

For the product category(ies)

Cobalt-chromium Powders for the manufacturing using laser sintering of dental prostheses (Class IIa) and orthopedic implants (Class IIb)

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2157665CN, initially dated 18 December 2012
Addendum, initially dated 3 March 2016

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 June 2018
Issued for the first time: 25 February 2016
Reissued: 13 July 2016

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2189673CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Metal powders for the manufacturing using laser sintering of dental prostheses (Class IIa) and orthopedic implants (Class IIb)

Issued to:

SINT-TECH
Parc Européen d'Entreprises
Rue Richard Wagner
63200 Riom
France

This certificate covers the following product(s):

• ST2724G

Initial date: 3 March 2016

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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