EC CERTIFICATE

Number: 2172878CE01

Full Quality Assurance System

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

Manufacturer:

BioComp Industries bv

Molenstraat 2a
5262 ED Vught
The Netherlands

For the product category(ies)

Implants and related instrument set, including accessories for Dental and Cranio Maxilla Facial (CMF) reconstruction

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 2085156CN, initially dated 1 June 2009
Addendum, initially dated 24 April 2015 and 1 February 2009

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 April 2023
Issued for the first time: 24 April 2015
Reissued: 6 April 2018

DEKRA Certification B.V.

Managing Director Certification Manager

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

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ADDENDUM

Belonging to certificate: 2172878CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Implants and related instrument set, including accessories for Dental and Cranio Maxilla Facial (CMF) reconstruction

Issued to:

BioComp Industries bv
Molenstraat 2a
5262 ED Vught
The Netherlands

This certificate covers the following product(s):

Implants and related instrument set, including accessories for **Cranio Maxilla Facial (CMF)** reconstruction:

- Extra Oral implants
- HAVD coated Extra Oral implants
- HA coated extra oral implants
- Extra Oral Abutments
- Healing Abutments
- Extra Oral Instruments
- Extra Oral Fixation devices

Initial date: 24 April 2015
Revised: 6 December 2018

DEKRA Certification B.V.

Managing Director Certification Manager

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ADDENDUM

Belonging to certificate: 2172878CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Implants and related instrument set, including accessories for cranio maxilla facial reconstruction

Issued to:

BioComp Industries bv
Molenstraat 2a
5262 ED Vught
The Netherlands

This certificate covers the following product(s):

Implants and related instrument set, including accessories for **Dental** reconstruction:

- Dental implants
- HA coated dental implants
- HAVD coated dental implants
- Dental Abutments
- Healing Abutments
- Dental Instruments
- Dental Fixation devices

Initial date: 1 February 2009
Revised: 6 December 2018

DEKRA Certification B.V.

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