

EC CERTIFICATE

Number: 2013772CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III)

Manufacturer:

Dyna Dental Engineering B.V.

Vang 9

4661 TX Halsteren

The Netherlands

For the product category(ies)

Dental Implants

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:

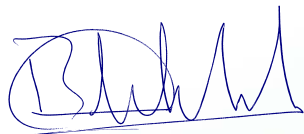
Certification Notice 2013772CN, initially dated 1 August 2001

Addendum, initially dated 1 August 2001

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 August 2023
Issued for the first time: 1 August 2001
Revised: 12 December 2019
Reissued: 1 August 2018

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
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: 2013772CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Dental Implants

Issued to:

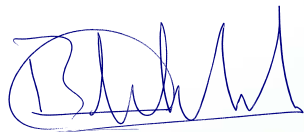
Dyna Dental Engineering B.V.
Vang 9
4661 TX Halsteren
The Netherlands

This certificate covers the following product(s):

Dental Implants

Initial date: 1 August 2001
Revision date: 12 December 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, sweeping initial 'J' followed by a series of connected loops.

J.A. van Vugt
Certification Manager

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