

# EC CERTIFICATE

Number: 2126204CE03

## Full Quality Assurance System

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

Manufacturer:

**PLAN 1 HEALTH S.R.L.**

Via Solari 5  
33020 Amaro (UD)  
Italy

For the product category(ies)

**Dental implants and related accessories (restorative components, dental instruments);  
extra oral implants and related accessories (restorative components, surgical  
instruments)**

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 2126204CN, initially dated 4 August 2009**  
**Addendum, initially dated 4 June 2015**

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 December 2019  
Issued for the first time: 4 June 2015  
Revised: 4 April 2016  
Reissued: 14 January 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



J.A. van Vugt  
Certification Manager

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands  
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

# ADDENDUM

Belonging to certificate: 2126204CE03

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

Dental implants and related accessories (restorative components, dental instruments); extra oral implants and related accessories (restorative components, surgical instruments)

Issued to:

### PLAN 1 HEALTH S.R.L.

Via Solari 5  
33020 Amaro (UD)  
Italy

This certificate covers the following product(s):

#### Dental Implants (Fixtures) (Class IIb):

- Fixture SyXFULL
- Fixture IHT
- Fixture IHC
- Fixture miniMAX
- Fixture GTB
- Fixture SyTISSUE
- Fixture SyEASY

#### Extra Oral Implants (Fixtures) (Class IIb):

- Fixture HEXCEL Extra

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A blue ink signature of G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of J.A. van Vugt, written in a cursive style.

J.A. van Vugt  
Certification Manager

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# ADDENDUM

Belonging to certificate: 2126204CE03

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

Dental implants and related accessories (restorative components, dental instruments); extra oral implants and related accessories (restorative components, surgical instruments)

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#### Restorative components (Class IIa):

- SyXFULL, IHC, IHT Restorative Components;
- Restorative Components HEXCEL Extra;
- Restorative Components SyXFULL;
- Restorative Components IHC & IHT;
- Restorative Components miniMAX;
- Restorative Components GTB;
- Restorative Components SyTISSUE;
- Restorative Components SyEASY

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Managing Director

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# ADDENDUM

Belonging to certificate: 2126204CE03

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

Dental implants and related accessories (restorative components, dental instruments); extra oral implants and related accessories (restorative components, surgical instruments)

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#### Dental and Extra-oral Implantology Instruments (Class Im, IIa)

- SyEASY, SyXFULL, IHC, IHT Instruments
- Compas Instruments
- miniMAX Instruments
- HEXCEL EXTRA Instruments
- GTB Instruments
- SyTISSUE Instruments
- SyEASY Instruments

Initial date: 4 June 2015

Revision date: 13 September 2018

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drs. G.J. Zoetbrood  
Managing Director



J.A. van Vugt  
Certification Manager

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