EC Certificate Full Quality Assurance System: BE06/761247

The management system of

DENTSPLY Implants NV

Research Campus 10
3500 Hasselt, Belgium

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 17 October 2014 until 24 February 2019 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 24 January 2017.
Issue 2. Certified since 1 October 2006.

Certification is based on reports numbered BE/AND 06/1247.QMD.

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
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SGS CE 01 0311 M2

DENTSPLY Implants NV

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 2

Detailed scope

Image processing system and software for simulating/evaluating dental orthodontic treatment i.e. dental bite options:
- SimPlant Ortho / Simplant O&O

Image processing system and preoperative software for simulating/evaluating dental implant and surgical options for oral implant and orthognatic treatment:
- SimPlant-software platform:

- **SimPlant Master**
- **SimPlant Pro**
- **SimPlant Planner**
- **SimPlant OneShot**
- **SimPlant View**
- **SimPlant Lab**
- **SimPlant Client**
- **SimPlant OMS**
- **SimPlant HMC**
- **SimPlant Go**

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

Additional facilities

Dentsply Implants N.V. (site Hasselt)
Research Campus 10
3500 Hasselt, Belgium

Dentsply Implants N.V. (site Leuven)
Grensstraat 1B
3010 Kessel-Lo, Belgium

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