ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

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

No. G1 18 03 97302 006

Manufacturer:

DENTSPLY Implants N.V.
Research Campus 10
3500 Hasselt
BELGIUM

Facility(ies):

DENTSPLY Implants N.V.
Research Campus 10, 3500 Hasselt, BELGIUM

DENTSPLY Ukraine LLC
Novovokzalna str 2, 03038 Kyiv, UKRAINE

DENTSPLY Implants N.V.
Kolonel Begaultlaan 1b, 3012 Leuven, BELGIUM

Product Category(ies):

Image processing System and preoperative Software for simulating / evaluating dental implant and surgical options for oral implant and orthognathic treatment

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713116697

Valid from: 2018-03-28
Valid until: 2022-02-24

Date, 2018-03-28

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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