ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 16 01 20326 053

Manufacturer:

Institut Straumann AG
Peter Merian-Weg 12
4002 Basel
SWITZERLAND

Facility(ies):

Etkon GmbH
Lochhamer Schlag 6, 82166 Gräfelfing, GERMANY

Institut Straumann AG
Gartenstrasse 143, 4002 Basel, SWITZERLAND

Institut Straumann AG
Peter Merian-Weg 12, 4002 Basel, SWITZERLAND

Etkon GmbH
Riquetstrasse 8 & Koburger Strasse 45, 04416 Markkleeberg, GERMANY

Straumann Manufacturing Inc
60 Minuteman Road, Andover MA 01810, USA

Straumann Villeret SA
Les Champs du Clos 2, 2613 Villeret, SWITZERLAND

Product Category(ies):

Implants, dental materials, prosthetic components, medical Software and their systems/instruments for use in oral and extraoral implantology (maxillo-facial surgery) and dental prosthetic restoration

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.

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Stefan Preiß

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

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