



Product Service

# CERTIFICATE

No. Q1N 16 01 20326 054

**Holder of Certificate:** Institut Straumann AG

Peter Merian-Weg 12  
4002 Basel  
SWITZERLAND

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production and Distribution of Implants, Dental Materials, Prosthetic Components, Planning and Design Software, Invasive and Non-Invasive Instruments, Auxiliary Components, Cassettes (Product and Product Related Services) for use in Oral and Extraoral Implantology (Maxillo-Facial Surgery) and Dental Prosthetic Restoration (see page 2 for additional locations)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** 713068898

**Valid from:** 2016-03-09  
**Valid until:** 2019-02-28



**Date,** 2016-03-09

*S. Preiß*  
Stefan Preiß

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**No. Q1N 16 01 20326 054**

**Applied  
 Standard(s):**

EN ISO 13485: 2012 + AC:2012  
 Medical devices - Quality management systems -  
 Requirements for regulatory purposes  
 (ISO 13485:2003 + Cor. 1:2009)  
 DIN EN ISO 13485:2012

**Facility (ies):**

**Institut Straumann AG**

Peter Merian-Weg 12  
 CH-4002 Basel, Switzerland

Quality Management System, Management Responsibility,  
 Resource Management, Product Realization including Product  
 Design, Production, Warehousing & Logistics, Purchasing &  
 Receiving

**Institut Straumann AG**

Gartenstrasse 143  
 CH-4002 Basel, Switzerland

Production, Warehouse Logistics and Distribution

**Etkon GmbH**

Lochhamer Schlag 6  
 D-82166 Gräfelfing, Germany

Design and Development of Planning and Design Software for  
 use in Oral and Extraoral Implantology (Maxillo-  
 Facial Surgery) and Dental Prosthetic Restoration

**Etkon GmbH**

Riquetstr. 8 & Koburger Strasse 45  
 D-04416 Markkleeberg

Production and Distribution of Prosthetic  
 Components and Dental Restorations and Dental Materials

**Straumann Villeret SA**

Les Champs du Clos 2  
 2613 Villeret Switzerland

Production of Implants, Prosthetic Components and Instruments  
 for Oral and Extraoral Implantology

**Straumann Manufacturing Inc**

60 Minuteman Road  
 Andover MA 01810 USA

Production of Implants, Prosthetic Components and  
 Instruments for Oral and Extraoral Implantology