EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60078931 0001

Report No.: 30791610 006

Manufacturer:
Sterngold Dental LLC
23 Frank Mossberg Drive
Attleboro MA 02703
USA

Products:
Design and Development, Production and Distribution of Dental Materials
Products: see attachment

Replaces Approval, Registration No.: HD 60023657 0001

Expiry Date: 2017-08-02

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. 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.

Effective Date: 2012-09-24

Date: 2012-09-24

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Jürgen Welte

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60078931 0001
Report No.: 30791610 006

Manufacturer:
Sterngold Dental LLC
23 Frank Mossberg Drive
Attleboro MA 02703
USA

Products: Dental Implant Products
Dental Prosthetic Products
Surgically Invasive Dental Instruments
Ceramic Crown & Bride Dental Alloys
Stern Restorative System

TÜV Rheinland LGA Products GmbH
TÜVRheinland®

Notified Body

Date: 2012-09-24

Jürgen Welte