EC Certificate

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

Registration No.: HD 60122293 0001

Report No.: 31692898 001

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 and Bridge Dental Alloys, and Dental Composites and Dental Cements used in the area of Dental Restorations.

Replaces Approval, Registration No.: HD 60078931 0001

Expiry Date: 2022-08-02

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: 2017-08-31

Date: 2017-08-31

Notified Body

M.Sc. M. Aihara

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.