TÜVRheinland®

# EC Certificate

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

**Registration No.:** HD 60134322 0001

**Report No.:** 15063506 003

**Manufacturer:**

Sure Dent Corporation
#809, 52, Sagimakgol-ro
Jungwon-gu
Seongnam-si, Gyeonggi-do, 13210
Republic of Korea

**Products:**

Gutta Percha Points, Sterile Absorbent Paper Points, Dental Root Canal Filling Material, Dental Root Canal Sealing Material, Dental Root Canal Cleanser and Impregnated Retraction Cord

Replaces Approval, Registration No.: HD 60133075 0001

**Expiry Date:** 2023-10-08

**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:** 2018-11-16

**Date:** 2018-11-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

**Notified Body**

M.Aihara

**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.**