TÜVRheinland®

EC Certificate

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

Registration No.: HD 60133075 0001

Report No.: 15063506 008

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 Cleansers
- Impregnated Retraction Cord

Replaces Approval, Registration No.: HD 60089049 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: 2018-10-09

Date: 2018-10-05

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.

Digitally signed by Benderschi Ruslan
Date: 2023.05.23 20:34:30 EET
Reason: MoldSign Signature
Location: Moldova

SUPER-DENT SRL