TÜVRheinland®

EC Certificate

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

Registration No.: HD 60145041 0001

Report No.: 12031467 004

Manufacturer:
B&E KOREA Co., Ltd.
995-16, Baran-ro, Jeongnam-myeon,
Hwaseong-si, Gyeonggi-do,
Republic of Korea

Products:
Dental etchant, Dental composite resin, Dental temporary filling materials, Dental temporary cement and Orthodontic adhesive

Replaces Approval, Registration No.: HD 60133343 0001

Expiry Date: 2023-10-14

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: 2020-04-29

Date: 2020-04-29

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle III

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.