

**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.  
#802, #807, B Dong, 60, Haan-ro  
Gwangmyeong-si, Gyeonggi-do 14322  
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



**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.