Business Stream Products
Certification Department

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LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

B&E KOREA Co., Ltd.
995-16, Baran-ro, Jeongnam-myeon,
Hwaseong-si, Gyeonggi-do, 18515
Republic of Korea

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date April 26, 2023

Application for: QMS

Certificate No.	: HD 60145041 0001
Requirement	: MDD Annex II excl. 4
Confirmation letter ID	: 2023-04-26_ HD 60145041 0001
Report no.	: 156147393-70

To whom it may concern,

Update of information to Certificate no. HD 60145041 0001, issued on 2020-04-29

The change notification received on 2022-07-06 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.
We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Revised Manufacturer address

Old Manufacturer address:	#807, #802, #804, B Dong, 60, Haan-ro, Gwangmyeong-si, Gyeonggi-do, 14322 Republic of Korea
New Manufacturer name:	995-16, Baran-ro, Jeongnam-myeon, Hwaseong-si, Gyeonggi-do, 18515 Republic of Korea

Best regards,

X Ning Chang

Ning N. C. Chang
Certification body

TÜV Rheinland
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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.

Digitally signed by Benderschi Tamara
Date: 2024.01.18 12:43:39 EET
Reason: MoldSign Signature
Location: Moldova