

EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number: 2195-MED-1733901

Manufacturer: B&E Korea Co., Ltd.
#807, #802, B Dong, 60, Haan-ro, Gwangmyeong-si, Gyeonggi-do, Korea

Product(s): Light Curing Dental Restorative Material

Model(s): B&F Flow (A1, A2, A3, A3.5, B1, B2, B3, OA2, OA3, I, INO, Core Blue, Core White, Core Yellow, Crown A2, Crown A3)

Reference Report No: MM0068-P002-R01, MM0068-P002-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 6 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s).

This EC certificate is valid till 2020-12-04.



Issue Date: 2017-12-05

Rukiye BALKAN
Deputy General Manager