



This is to certify that the Quality Management System of

**B&E BIO-TECHNOLOGY CO., LTD.**

Unified Social Credit Code : 91370613706324453C

Operation Address : No.11 Jie'aisi Road, Laishan District, Yantai City, Shandong Province, China

Registered Address : No.11 Jie'aisi Road, Laishan District, Yantai City, Shandong Province, China

applicable to

The design, development, production and sales of electrolyte analyzer & ISE reagents for use on the electrolyte analyzer, quality control products and calibrators for use on the electrolyte analyzer, hematology analyzer, reagents for use on the hematology analyzer, calibrator and quality control for use on the hematology analyzer , reagents for use on the urinalysis analyzer(products involving license qualification are limited to the scope of license qualification)

has been assessed and registered by NQA against the provisions of

**ISO 9001:2015**

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website ([www.cnca.gov.cn](http://www.cnca.gov.cn))

SNQA's website : [www.snqa.com.cn](http://www.snqa.com.cn)

Managing Director

Certificate Number

**42713**

Date:

12 October 2016

Reissue Date:

16 October 2020

Valid Until:

14 September 2021

EAC Code:

19/13



015







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has been assessed and registered by NQA against the provisions of

**ISO 13485: 2016**

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

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SNQA's website : [www.snqa.com.cn](http://www.snqa.com.cn)

Managing Director

Certificate Number

**31107**

Date:

18 July 2008

Reissue Date:

16 October 2020

Valid Until:

25 September 2021

EAC Code:

19/13/34



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## 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&E 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 5 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

This version of certificate has come into force on 23.03.2017. 1/1 2195-MED-1733901