

**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60143320 0001

**Report No.:** 15096007 006

**Manufacturer:** ChangZhou BoMedent Medical  
Technology Co., Ltd.  
No.9 Changyang Road, West Taihu Science  
and Technology Industrial Park  
Changzhou  
213000 Jiangsu  
China

**Products:**

- Dental Electrical Motors
- Apex Locators

Replaces Approval, Registration No.: DD 60123245 0001

**Expiry Date:** 2024-05-27

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2019-09-30

**Date:** 2019-09-30

Notified Body



Herbert Zhang

**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.