EC Certificate

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

Registration No.: DD 60123245 0001

Report No.: 15096007 002

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 60116425 0001

Expiry Date: 2021-10-04

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: 2017-11-01

Date: 2017-11-01

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
III
Zertifizierungsstelle

S. Liu

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.