EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60144008 0001

Report No.: 17047780 009

Manufacturer:

Aidite (Qinhuangdao) Technology
Co., Ltd.
No. 9 Dushan Road, Economic And
Technological Development Zone
Qinhuangdao City
066004 Hebei
China

Products:

- Dental Zirconia Ceramics
- Dental Glass Ceramics
- Coloring Liquid Specializeds for Aidite Zirconia Material
- Porcelain Powder
- PMMA Blocks for Dental Use

Replaces Approval, Registration No.: HD 60139224 0001

Expiry Date: 2024-05-27

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: 2019-12-02

Date: 2019-12-02

Notified Body

Fuxiu Sheng

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.