

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

Registration No.: DD 60147763 0001

Report No.: 15096178 005

Manufacturer: Shanghai New Century Dental
Materials Co., Ltd.
No. 461 Tanghang Village
Huating Town
Jiading District
201816 Shanghai
P.R. China

Products:

Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: DD 60135703 0001

Expiry Date:

2024-05-26

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:

2020-03-19

Notified Body

Date:

2020-03-19

Jason Pan



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.



Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60147763 0001
Report No.: 15096178 005

Manufacturer: Shanghai New Century Dental
Materials Co., Ltd.
No. 461 Tanghang Village
Huating Town
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201816 Shanghai
P.R. China

Products:

- Multi-layer Synthetic Resin Teeth
- Denture Base Materials
- Dental Cements
- Dental Zirconia Ceramics

Site included:

5th Floor, Jinyuan Building, 1218 Yongsheng Road,
Jiading, Shanghai, China

Notified Body

Date: 2020-03-19

Jason Pan
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