



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

Registration No.: DD 60139781 0001

Report No.: 15068621 011

Manufacturer: Zhejiang Protect Medical
Equipment Co., Ltd.
Science & Technology Zone
Xiaofeng Town
313301 Anji City, Zhejiang
China

Products: Orthodontic Materials and Instruments
(see attachment for products included)
Replaces Approval, Registration No.: DD 60093947 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: 2019-06-17

Date: 2019-06-17



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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60139781 0001
Report No.: 15068621 011

Manufacturer: Zhejiang Protect Medical
Equipment Co., Ltd.
Science & Technology Zone
Xiaofeng Town
313301 Anji City, Zhejiang
China

Products:

- Orthodontic Metal Brackets
- Orthodontic Ceramic Brackets
- Orthodontic Bands
- Orthodontic Buccal Tubes
- Orthodontic Lingual Sheaths
- Orthodontic Crimpable Hooks
- Orthodontic Power Hooks
- Orthodontic Lingual Buttons
- Orthodontic Niti Archwires
- Orthodontic Elastics

Date: 2019-06-17

Notified Body



Fuxiu Sheng

