

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Shanghai Fanta Dental Materials  
Co., Ltd.**  
Room 1215, Building 4  
No.6558 Ting Wei Rd., Jinshan Dist  
201500 Shanghai  
China

has established and applies a quality management system for medical devices  
for the following scope:

**Manufacture and Distribution of Medical Devices**  
(see attachment for products and site included)

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-01-08  
Certificate Registration No.: SX 60125025 0001  
An audit was performed. Report No.: 15096179 001  
This Certificate is valid until: 2020-12-14

Certification Body



Date 2018-01-08



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

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

**Registration No.:** DD 60125024 0001

**Report No.:** 15096179 001

**Manufacturer:** Shanghai Fanta Dental Materials  
Co., Ltd.  
Room 1215, Building 4  
No.6558 Ting Wei Rd., Jinshan Dist  
201500 Shanghai  
China

**Products:** Orthodontic Brackets, Orthodontic Archwires,  
Orthodontic Bands, Orthodontic Buccal Tubes,  
Dental Root Canal Instruments  
  
(see attachment for site included)

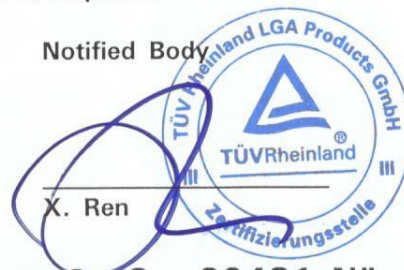
**Expiry Date:** 2022-12-14

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:** 2018-01-08

**Date:** 2018-01-08

Notified Body



**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 60125024 0001  
**Report No.:** 15096179 001

**Manufacturer:**

Shanghai Fanta Dental Materials  
Co., Ltd.  
Room 1215, Building 4  
No.6558 Ting Wei Rd., Jinshan Dist  
201500 Shanghai  
China

**Site included:**

Shanghai Fanta Dental Materials Co., Ltd.  
Room J803, No. 75, East Tianlin Road,  
Xuhui Dist, 200233 Shanghai, China

**Date:** 2018-01-08

**Notified Body**



**X. Ren**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60125025 0001

**Report No.:** 15096179 001

**Organization:**

Shanghai Fanta Dental Materials  
Co., Ltd.  
Room 1215, Building 4  
No.6558 Ting Wei Rd., Jinshan Dist  
201500 Shanghai  
China

**Scope:**

**Products:**

Orthodontic Brackets, Orthodontic Archwires,  
Orthodontic Bands, Orthodontic Buccal Tubes,  
Dental Root Canal Instruments

**Site included:**

Shanghai Fanta Dental Materials Co., Ltd.  
Room J803, No. 75, East Tianlin Road,  
Xuhui Dist, 200233 Shanghai, China

Manufacture and Distribution of the a.m. products

**Certification Body**



**Date:** 2018-01-08

