











Precisely Right.

Business Stream Products Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Shenzhen Xiangtong Co., Ltd. 2nd Floor, 1st Building, West Area Honghualing Industrial Park No.88, North Zhuguang Rd. Nanshan District 518055 SHENZHEN **CHINA**

Application for : Vollst. QMS, Anhang II MDD

Certificate No. : HD 60136932 Sheet 0001 Device : Only for QM-System audit Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate No. HD 60136932 0001.

Kind regards

Certification body

Test sample: no, documentation available

Contact

Tel. +49 911 655-522 Mail service@de.tuv.cor

Date May 10, 2019

TÜV Rheinland LGA Products GmbH

Tillystraße 2 90431 Nürnberg

Tel. +49 911 655-5225 Fax +49 911 655-5226 Mail service@de.tuv.com Web www.tuv.com/safety

Board of Management

Dipl.-Ing. Jörg Mähler, Spokesman

Dipl.-Kfm. Dr. Jörg Schlösser

Chairman of the Supervisory Board

Dipl.-Ing. Ralf Scheller

Nuremberg HRB 26013 VAT No.: DE 811835490







EC Certificate

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

Registration No.: HD 60136932 0001

Report No.: 17062390 004

Manufacturer:

Shenzhen Xiangtong Co., Ltd.
2nd Floor, 1st Building, West Area
Honghualing Industrial Park
No.88, North Zhuguang Rd.
Nanshan District
518055 Shenzhen
China

Products:

- Zirconia Dental Ceramics
- Dental Base Metal Alloys

(see attachment for site included)

Expiry Date: 2024-02-26

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:

2019-05-10

Date:

2019-05-10

Notified Body

M.Sc. M. Aihara

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.

TÜVRheinlan



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate

Registration No.:

HD 60136932 0001 17062390 004

Manufacturer:

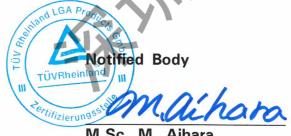
Report No.

Shenzhen Xiangtong Co., Ltd. 2nd Floor, 1st Building, West Area Honghualing Industrial Park No.88, North Zhuguang Rd. **Nanshan District** 518055 Shenzhen China

Site included:

DONGGUAN XIANGTONG CO., LTD 2-1 Xida Road, Bai Huadong Village, Da Lingshan Town, Dongguan, Guangdong, 523000, China

Date: 2019-05-10



M.Sc. M. Aihara