Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

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

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date May 10, 2019

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

Aihara

M.Sc. M. Aihara

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
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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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
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

Site included:

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

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2019-05-10

M.Aihara

M.Sc. M. Aihara