EC Certificate

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

Registration No.: DD 60148503 0001

Report No.: 50307116 002

Manufacturer:
Shanghai Xing Yu Medical Equipment
Co., Ltd.
3 Floor, Building 21, No.3825 Xin Zhuan Road
Dong Jing Town, Song Jiang District
201601 Shanghai
P.R. China

Products:
- Gutta Percha Points
- Sterile Absorbent Paper Points
- Dental Root Canal Instruments

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: 2020-06-23

Date: 2020-06-23

Notified Body

Jing Zhang

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.

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Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Shanghai Xing Yu Medical Equipment
Co., Ltd.
3 Floor, Building 21, No.3825 Xin Z
201601 SHANGHAI
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Contact

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Mail service@de.tuv.com

Date June 23, 2020

Application for : QMS Produktion, Anhang V MDD
Certificate No. : DD 60148503 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. DD 60148503 0001.

Kind regards

Certification body

Jing Zhang

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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