

EC DECLARATION OF CONFORMITY

Manufacture's Name: Shanghai Xing Yu Medical Equipment Co., Ltd.

Manufacture's Address: 3rd Floor, Building 21, No. 3825 Xin Zhuan Road, Dong Jing Town, Song Jiang District, 201601, Shanghai, China.

European Representatives: Luxus lebenselt welt GmbH

Kochstr. 1, 47877, Willich, Germany

Name of the Products:

Sterile Absorbent Paper Points-medical device Class II A.

(Sterile Absorbent Paper Points include: Absorbent Paper Points- size from 10# to 140#.)

Gutta Percha Points-medical device Class II A.

(Gutta Percha Points include : Gutta Percha Points - size from 10# to 140#.)

Dental Root Canal Instruments -medical device Class II A.

(Dental Root Canal Instruments include: K-Files Stainless steel - size from 6# to 140#; K-Files Nickel- Titanium - size from 6# to 140#; H-Files Stainless steel - size from 6# to 140#; H-Files Nickel -Titanium - size from 6# to 140#; R-Files Stainless steel - size from 6# to 140#; R-Files Nickel -Titanium - size from 6# to 140#.)

Conformity Route: Self Declaration

We hereby declare that the manufacturer's quality system was audited in accordance with the requirements of Annex v of the directive 93/42/EEC on medical devices. We certify that the quality system meets the requirements of the aforementioned directive. The present certificate is subjected to the surveillance required by annex v section 4.

Referenced standards: 93/42/EEC Medical Devices

European Notified Body: CONFORMITE EUROPEENNE 0197

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