EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

SINO-DENTEX CO.,LTD.

Xiao Ping

12358 Haoyue Road, Changchun, Jilin 130062,

393 Grosvenor Street, Manchester M1

China

7HS, UK

We, the manufacturer, herewith declare that the products

Dental Resin Composite

Dental Adhesive

Dental Etchant

Dental Cement

Model: see attached

(including system components and accessories)

UMDNS-Code: 16736

UMDNS-Code: 10034

UMDNS-Code: 17737

UMDNS-Code: 16707

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

C € 0197

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland Product Safety GmbH Am Grauen Stein D-51105 Köln

Certificate No.: DD 6011 0386 0001

Issue date: 2016-06-28

Expiry date: 2020-04-09

following the procedure relating to the EC Declaration of Conformity set out in Annex VII coupled with Annex V) of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of

SINO-DENTEX CO., LTD. Pengtow Yan

Management Representative

Legally binding signature, Function

2016-04-10