

EC Declaration of Conformity

Manufacturer:

United Dental Changzhou
B1 Building No 9, Chang Yang Rd, Wujin District,
Changzhou, Jiangsu P.R. China, 213100

whose single Authorized Representative:

Prolinx GmbH
Brehmstr. 56, 40239, Duesseldorf,
Germany

We, the manufacturer, herewith declare that the products

Root canal File
UMDNS-Code: 16662

Irrigation needle:
UMDNS-Code: 17946

Plugger:
UMDNS-Code: 16460

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

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



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

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

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

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Sep. 11, 2020

