

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
CONCERNING MEDICAL DEVICES**



Manufacturer: Guangzhou Fengdan Medical Equipment Co., Ltd.

Medical Device: Integral dental unit (except for dental turbine handpiece, toothdrill and the suction head, including handpiece cable, valves)

Model: QL2028, QL2028I, QL2028II, QL2028III, QL2028IV, BZ636, BZ637, BZ638, BZ639

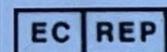
Classification - Annex IX: Class IIa, Rule 5,9

Conformity assessment Route: Annex V

We, Guangzhou Fengdan Medical Equipment Co., Ltd.,

Office Address: No .286, Caixin Road, Lanhe Town, Nansha District, Guangzhou City, Guangdong Province 511480, P.R.China. All supporting documentation is retained at the premises of the manufacturer.

European representative: Wellkang Ltd



Enterprise Hub, NW Business Complex, 1 Beraghore Rd.
Derry, BT488SE, Northern Ireland

declare at our sole responsibility that products Integral Dental Unit, model: QL2028, QL2028I, QL2028II, QL2028III, QL2028IV, BZ636 and falling class IIa, rule 5,9 comply with requirements of directive 93/42/EEC of 14 June 1993 concerning medical devices; including, at 21 March 2010, the amendments by council directive 2007/47/EEC.

NOTIFIED BODY

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1639, has performed ANNEX V and issued the certificate.

(EC) Certificate(s): CN19/41121

Start of CE-marking: 16 March 2012

Date of declaration: 10 March 2024

Place, Date of Declaration:

China Guangdong Province 10 March 2024

Signature:



Name: Calvin Chen

Position: responsible senior executive of manufacturer