

**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

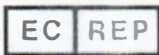
Classification - Annex IX: Class IIa, Rule 5.9

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, BT48 8SE Derry, United Kingdom  
(Northern Ireland only)

Importer / Distributor: Nastimed Serv S.R.L., 1 Mihai Eminescu, Cluj Napoca, Romania

declare at our sole responsibility that products Integral Dental Unit, model: QL2028, QL2028I, QL2028II, QL2028III, QL2028IV, BZ636, BZ637, BZ638, BZ639 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

SGS Belgium NV

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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: 2022.12.30

Place, Date of Declaration:

China Guangdong Province 2022.12.30

Signature:

  
Name: Calvin Chen  
Position: responsible senior executive of manufacturer