

**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)

Model: QL2028,QL2028I,QL2028II,QL2028III,QL20208IV,BZ636,BZ637,BZ638,BZ639

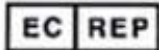
Classification - Annex IX: Class IIa, Rule 5,9

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: S.C. NASTIMED SERV S.R.L



Str.m.Eminescu, nr 1, Cluj Napoca, Romania

declare at our sole responsibility that products Integral Dental Unit, model: QL2028,QL2028I,QL2028II,QL2028III,QL20208IV,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: SGS Belgium NV

SGS House Noorderlaan 87 2030 Antwerp Belgium

Country: Belgium

Website: www.sgs.com



1639, has performed ANNEX V and issued the certificate.

(EC) Certificate(s): CN19/41121

Start of CE-marking: 16 March 2012

Date of declaration: 2021.5.31

Place, Date of Declaration: China Guangdong Province 2021.5.31

Signature:



Name: Calvin Chen

Position: responsible senior executive of manufacturer